K092177

OCT 1 5 2009

## 510(k) Summary

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR Part 807, Section 807.92(c).


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Date Prepared: July 17, 2009

Device Information

Trade Name: MO.MA® ULTRA Proximal Cerebral Protection Device
Common Name: Cerebral Protection Device
Regulation Name: Catheter, carotid, temporary, for embolization capture

Predicate Device

- GORE Flow Reversal System (K083300)

Device Description

The MO.MA® ULTRA Proximal Cerebral Protection Device consists of a multi-lumen shaft integrating two compliant occlusion balloons. The device is packaged with one hollow mandrel, one hemostatic valve with two-way stopcock and extension tubing, three 40 µm filter baskets, one 30 cc syringe with male luer, one T-safety connector and two 1-way stopcocks.

The MO.MA® ULTRA Proximal Cerebral Protection Device achieves cerebral protection by occluding the common carotid artery (CCA) and the external carotid artery (ECA) with two

compliant balloons. Occluding the CCA and ECA produces blockage of antegrade and retrograde blood flow at the carotid bifurcation to prevent distal embolization of particulate debris and allow removal of particulate debris by blood aspiration.

Indications for Use

The MO.MA® ULTRA Proximal Cerebral Protection Device is indicated as an embolic protection system to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting procedures involving lesions of the internal carotid artery and or the carotid bifurcation. The reference diameter of the external carotid artery should be between 3-6 mm and the reference diameter of the common carotid artery should be between 5-13 mm.

Technological Characteristics

- The MO.MA® ULTRA Proximal Cerebral Protection Device has the similar design, materials and fundamental technology as the previously cleared GORE Flow Reversal System (K083300).

Performance Data

Non-clinical testing of the MO.MA® ULTRA Proximal Cerebral Protection Device consisted of performance testing, biocompatibility, sterilization, packaging, and product shelf life testing. These tests demonstrated that the technological characteristics such as product performance, design and intended use are substantially equivalent to the currently marketed predicate device. A GLP animal study was conducted to support the safety and performance of the device prior to the pivotal clinical study.

**Clinical Data:** The ARMOUR study was a pivotal, prospective, multi-center, non-randomized study with sequential enrollment of all qualified patients undergoing carotid interventional procedures. All eligible patients who provided informed consent and met inclusion/exclusion criteria underwent percutaneous revascularization of the carotid artery using the Mo.Ma™ Proximal Cerebral Protection Device and a stent approved by the FDA for carotid artery stenting. Follow-up took place at pre-discharge and at 30 days post-procedure. Results were compared to a performance goal for the 30-day major adverse cardiac and cerebrovascular events (MACCE) composite rate, which was derived from previous carotid stenting trials. A total of 262 patients were enrolled at 25 sites in the United States and in Europe. 184 patients were enrolled at 20 sites in the US and 78 patients were enrolled at 5 sites in Europe. The primary endpoint results of the trial were successful compared to the established performance goal and thus demonstrated the safety and efficacy of the Mo.Ma™ device.

Conclusion

Based on similar intended use, technological characteristics, and performance characteristics, the MO.MA® ULTRA Proximal Cerebral Protection Device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Invatec, Inc.
ATTN: Steve Camp
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3101 Emrick Blvd., Suite 113
Bethlehem, PA 18020

OCT 15 2009

Re: K092177
Trade/Device Name: MO.MA ULTRA Proximal Cerebral Protection Device
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NTE
Dated: October 6, 2009
Received: October 7, 2009

Dear Mr. Camp:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## 5 STATEMENT OF INDICATIONS FOR USE

**Indications for Use**

510(k) Number (if known): K092177

Device Name: MO.MA® ULTRA Proximal Cerebral Protection Device

Indications for Use:

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Prescription Use __X__ (21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Donna R. Vachon

(Division Sign-Off)
Division of Cardiovascular Devices

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